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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,072	09/22/2005	Mylene Weill	263365US0X PCT	5727

  

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EXAMINER	
NASHED, NASHAAT T	

  

ART UNIT	PAPER NUMBER
1656	

  

NOTIFICATION DATE	DELIVERY MODE
09/24/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/518,072	<b>Applicant(s)</b> WEILL ET AL.	
	<b>Examiner</b> NASHAAT T. NASHED	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24 and 26-41 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29,30 and 32-41 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

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The application is amended as requested in the communication filed August 23, 2010. Accordingly, claims 1-23 and 25 are canceled; claims 24 and 26-28 are amended and new claims 29-41 are entered. Claims 24, and 26-28 remain withdrawn from further consideration.

Claims 29-41 are under consideration in this Office action.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicant made a commendable effort to remove the embedded hyperlinks and the disclosure as amended contain few left. See for example the amendment to the specification at page 6, third line from the bottom, and the specification at page 32, line 23.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The phrases "similar" in claim 29 and "similarity" in claim 33 render the claims indefinite because the resulting claim does not define the metes and bound of the desired patent protection. It is noted that the phrase is defined in the specification at page 6, line 16-28. The definition, however, does not define the metes and bound in the phrase with any particularity. No penalties are assessed on gapes and insertion, or description of what is conservative substitution and what is not. Applicants have not responded to this rejection.

(b) Claims 34, 37, and 39 contain a reference to an amino acid at position 119 from undefined sequence, which renders the claims indefinite because the resulting claims do not define the metes and bound of the desired patent protection. For examination purposes only is ignored.

(c) Claim 37 is dependent from canceled claim, which renders the claim indefinite.

(c) Claims 30-33, 35, 36, 38, 40-41 are included in this rejection because it is dependent from rejected claims and does not cure their deficiencies.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to all possible polypeptide having 90% identity and 95% similarity to SEQ ID NO:1. The specification, however, only provides SEQ ID NO: 3, 5, and 126 comprising SEQ ID NO: 1 and SEQ ID NO: 7, 57 and 122 comprising an amino acid sequences having 94.3%, 94.1 and 99.8% identical to SEQ ID NO:1 encompassed by these claims.

The court of Appeals for the Federal Circuit has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] name chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *UC California v. Eli Lilly* (43 USPQ2d 1398). For claims drawn to genus, MPEP section 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Also, MPEP section 2163 states that a representative number of species mean that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. At the time of invention, polypeptides comprising SEQ ID NO:1 having acetylcholinesterase were not known and the application discloses only several species comprising amino acid sequences >94% identical to SEQ ID NO:1. Thus, the specification fails to describe additional representative species of these insect acetylcholinesterase by any identifying structural characteristics or properties other than that they contain catalytic region >94% identical to SEQ ID NO: 1, for which no predictability of function is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Applicants may overcome this rejection by inserting functional language in the claim.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 30, and 32-41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bourguet *et al.* (Bourguet A, IDS Reference: J. Neurochemistry 1996, 67 (5), 2115-2123).

Claims 29, 30, and 32-41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bourguet *et al.* (Bourguet B, IDS Reference: Biochemical Genetics 1996, Vol 34, 351-362).

In response to the above rejections, applicants deleted the examined claims and filed claims 29-41. They argue that the rejection does not apply to the new claim and compared the activities of AChE1 and some other cholinesterase reported in the cited prior art. Also, applicants filed a declaration by Dr. Fort.

Applicants' arguments filed 8/23/10 have been fully considered, and they are found unpersuasive. Applicants contended that the teaching of Bourguet A and Bourguet B does not include a purified protein and that the preparation of the prior art is just an extract. An extract meet the limitation of isolated and purified. The claim does not define a degree of purity. Also, applicant argue repeatedly that the prior art does not teach the amino acid sequence of SEQ ID NO:1. The examiner agrees that the prior art does not teach any amino acid sequence, and therefore claim 31 limited to SEQ ID NO:1 is not included in this rejection and indicated as allowable below. The rest of the claims, however, are not limited to a particular amino acid sequence. The isolated acetylcholine esterase of the prior art meet all the limitation of the claim. It is isolated or purified acetylcholine esterase from the same biological source as the claimed acetylcholine esterase. Applicants have the burden of distinguishing the claimed acetylcholine esterase from those of the prior art.

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Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NASHAAT T. NASHED whose telephone number is (571)272-0934. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nashaat T. Nashed/  
Primary Examiner, Art Unit 1656